

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/207,168 12/07/98 HINUMA

S 48811

EXAMINER

HM22/0702

DIKE BRONSTEIN ROBERTS & CUSHMAN
INTELLECTUAL PROPERTY PRACTICE GROUP
EDWARDS & ANGELL
P O BOX 9169
BOSTON MA 02209

ROMEQ, D

ART UNIT

PAPER NUMBER

1647

DATE MAILED:

07/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

BEST AVAILABLE COPY

Office Action Summary

Application No.
09/207,168

Applicant(s)

Hinuma et al.

Examiner

David Romeo

Art Unit

1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 Apr 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above, claim(s) 9-17, 19, 21-23, and 25-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 18, 20, and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Art Unit: 1647

DETAILED ACTION

1. The amendment filed 4/20/2001 (Paper No. 11) has been entered. Claims 1-34 are pending. Claims 9-17, 19, 21-23, 25-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Claim 20 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) to the extent that it is drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8. Claims 1-8, 18, 20, 24 are being examined to the extent that they read upon SEQ ID NOs: 1-7, 35-43. Any objection and/or rejection of record that is not maintained and/or repeated in this Office action is withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Acknowledgment is made of applicant's claim for foreign priority based on applications filed in Japan on 06/06/96, 09/19/96, and 10/15/96. It is noted, however, that applicant has not filed certified copies of the applications as required by 35 U.S.C. 119(b). It is acknowledged that Applicants will file a supplemental response enclosing certified copies.

3. The application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Specifically, the specification fails to recite the appropriate sequence identifiers at each

Art Unit: 1647

place where a sequence is discussed. See for example page 13. This is not meant to be an exhaustive list of places where the specification fails to recite the appropriate sequence identifiers at each place where a sequence is discussed. The application cannot issue until it is in compliance, i.e. until the specification recites the appropriate sequence identifier at each place where a
5 sequence is discussed. Nucleic acid sequences with 10 or more nucleotides, at least 4 of which are specifically defined, must comply with the sequence rules. Amino acid sequences with 4 or more residues, at least 4 of which are specifically defined, must comply with the sequence rules.

Correction is required.

It is acknowledged that Applicants will submit a new sequence listing.

- 10 4. Claims 1, 2, 4-6, 18, 20, 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprising the amino acid sequence of SEQ ID NO: 1, does not reasonably provide enablement for a deleted or substituted variant thereof without respect to the functional activity thereof. Applicants' arguments have been fully
15 433. The specification at pages 22-27 provides for the deletion of N- or C-terminal residues, or

¹Citations by the examiner are in an alphanumeric format, such as "(a1)", wherein the "a" refers to the reference cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

Art Unit: 1647

the substitution of Lys for the 6th residue Arg in SEQ ID NO: 38. The claims are not limited to the deletions from the N- or C-termini and encompass any and all deletions, substitutions, or insertions of any 1 to 5 amino acid residues and there are no functional limitations to substituted, inserted polypeptide. The specification lacks guidance for using a polypeptide that does not have the desired activity. The skilled artisan is left to extensive, random, trial and error experimentation in order to determine how to use a polypeptide that does not have the desired activity. Such extensive, random, trial and error experimentation is considered undue.

5. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition comprising a polypeptide comprising the amino acid sequence of SEQ ID NO: 1, does not reasonably provide enablement for the intended uses of claim 20. Applicants' arguments have been fully considered but they are not persuasive. The "Background Art" at page 2 provides "various derivatives of somatostatin have been synthesized and tried for clinical application for the purpose of inhibiting hormone hypersecretion or tumor growth". However, essentially and/or potentially any and all compounds could be "tried for clinical application for the purpose of inhibiting hormone hypersecretion or tumor growth". The ability of a compound to be tried "for the purpose of inhibiting hormone hypersecretion or tumor growth" does not mean that a compound can be used for the treatment or prevention of "hormone hypersecretion or tumor growth".

Art Unit: 1647

6. Claim(s) 1, 2, 7, 8, 18, 20, 24 are rejected under 35 U.S.C. § 112, second paragraph, because they recite the term "precursor". Applicants' arguments have been fully considered but they are not persuasive. The specification at page 28 indicates that a precursor may be any peptide that contains a peptide of the present invention. However, the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "precursor" an artisan cannot determine what additional limitations are placed upon a claim by the presence of this term.

7. Claim 20 is rejected under 35 U.S.C. § 112, second paragraph, over the recitation of "a neural activity or sleep modulator" because it is unclear which neural activity is intended and it is unclear if the "modulation" is stimulation or inhibition. Applicants' arguments have been fully considered but they are not persuasive. Although the specification refers at page 2 to a journal supposing that cortistatin acts as a modulator of neural activities and sleep, in the instant application it is unclear which neural activity is intended and it is unclear if the "modulation" is stimulation or inhibition.

8. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Andrews (CA, cited by Applicants). Applicants' arguments have been fully considered but they are not persuasive. Andrews teaches a peptide SS-37 (Abstract) that comprises the amino acid sequence of SEQ ID

Art Unit: 1647

NO: 43, wherein said peptide does not comprise the amino acid sequence of SEQ ID NO: 31 or 32.

New formal matters, objections, and/or rejections:

Claim Rejections - 35 USC § 102

5 9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

10 (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. Claims 1-8, 18, 20, 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Olsen

(a12). This rejection is based upon priority of Olsen to provisional application no. 60/033,980,

filed on December 31, 1996. Olsen teaches polypeptides comprising the amino acid sequence of

15 Olsen's SEQ ID NO: 2 or 4, analogs thereof wherein not more than 5 or 3 amino acids are

substituted (column 16, lines 45-52), and a pharmaceutical composition comprising same (column

29, lines 38-47). Presumably, the pharmaceutical compositions would comprise a salt of the

polypeptide. Olsen's SEQ ID NO: 4 is a polypeptide comprising the amino acid sequence of the

instant application's SEQ ID NO: 1, 2, 3, 4, 35, 36, or 37, or a precursor thereof. Olsen's SEQ ID

Art Unit: 1647

NO: 2 is a polypeptide comprising an amino acid sequence derived from the amino acid sequence of SEQ ID NO: 1 by substitution of one amino acid residue.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See
5 MPEP § 201.15.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

10 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen (a12) as
15 applied to claim 1 above. Olsen teaches a polypeptide comprising the amino acid sequence of Olsen's SEQ ID NO: 2. Olsen's SEQ ID NO: 2 is a polypeptide comprising an amino acid sequence derived from the amino acid sequence of SEQ ID NO: 1 by substitution of one amino acid residue. Specifically, the substitution of Arg for Xaa. In Olsen's SEQ ID NO: 4, a subfragment of SEQ ID NO: 2, Xaa is Arg. Olsen does not teach a polypeptide comprising the
20 amino acid sequence of the instant application's SEQ ID NO: 5, 6, or 7. However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention that Xaa in

Art Unit: 1647

Olsen's SEQ ID NO: 2 is Arg because in Olsen's SEQ ID NO: 4, a subfragment of SEQ ID NO: 2, Xaa is Arg. Olsen's SEQ ID NO: 2 wherein Xaa is Arg is a polypeptide comprising the amino acid sequence of SEQ ID NO: 5, 6, or 7. The invention is prima facie obvious over the prior art.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because
5 a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Conclusion

13. No claims are allowable.

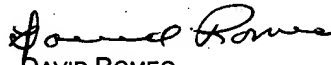
10 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

15 OFFICIAL PAPERS FILED BY FAX SHOULD BE DIRECTED TO (703) 308-4242.

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

20 
DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

JUNE 29, 2001